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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,764	09/27/2000	Joseph R. Pisegna	M-8978 US	7433

22798 7590 11/27/2002

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.
P O BOX 458
ALAMEDA, CA 94501

EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 11/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/671,764

Applicant(s)

PISEGNA ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 13-19 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 20-29 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because alterations to the addresses of inventors, Joseph R. Pisegna and Stephen Wank, which have not been initialed and dated as are required by 37 CFR 1.52(c).

Election/Restrictions

2. Applicant's election of Group I, claims 1-12, 20-29 and 31 in Paper No. 15 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Sequence Listing

3. The amendment filed May 14, 2002 regarding the sequence listing is acknowledged, and CRF has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-12, 21-29 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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5. Claim 1-12 are indefinite because the claims lack essential steps in the method of increasing the efficacy of a gastric H^+/K^+ -ATPase pump inhibitor. The omitted step is the end point of the process. Claims 2-12 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

6. Claim 2 is indefinite because the claim depends from itself.

7. Claims 2-10, 21-29 and 31 are indefinite because of the use of the term “a pentagastrin, a gastrin, or analogue thereof is pentagastrin”. The term “a pentagastrin, a gastrin, or analogue thereof is pentagastrin” renders the claim indefinite, it is unclear whether there is any difference between “a pentagastrin” and “pentagastrin”, and how a gastrin can also be a pentagastrin.

Claims 3-10 and 22-29 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

8. Claim 21 is indefinite because the claim depends from a claim with a higher claim number.

9. Claim 22 is indefinite because of the use of the term “and or”. The term “and or” renders the claim indefinite, it is unclear whether the limitation after “and or” is included or not, and if included is to be read as an alternative “or” or the conjunctive “and”. Use either “or” or “and” not both.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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10. Claims 1, 2, 5, 6, 7 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Simon *et al.* (Aliment. Pharmacol. Therap. 4, 239-245 (1990)).

Simon *et al.* teach the effects of the H^+/K^+ -ATPase inhibitor, BY1023/SK&F 96022 on the pentagastrin-stimulated acid secretion in healthy male volunteers, and intravenous administration of BY1023/SK&F 96022 induced a rapid and dose-dependent inhibition of pentagastrin-stimulated acid secretion, where the inhibitory effect lasted longer than the measurement period, 3 hours (abstract, page 241, Fig. 2; claims 1, 2, 5 and 11). Pentagastrin is continuously infused, and one hour after the start of the pentagastrin infusion, the proper dose of BY1023/SK&F 96022 or placebo is administered intravenously (page 241, claims 6 and 7).

11. Claims 1 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Murphy *et al.* (U. S. Patent 4,997,950).

Murphy *et al.* teach analogs from C-terminus of gastrin act as potent and specific antagonists of gastrin-stimulated acid secretion (column 1, lines 6-10), these analogs can be used in adjunctive therapy with drugs such as omeprazole, a H^+/K^+ -ATPase inhibitor (column 2, lines 24-31) in animal models (column 5, claims 1 and 12). The analogs of gastrin have the inherent property of increasing the efficacy of the H^+/K^+ -ATPase inhibitor, omeprazole, thus, the claimed invention is anticipated by the reference.

Conclusion

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CHK*
Patent Examiner

November 26, 2002

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600